

## REMARKS

Claim 1 has been amended to recite that:

- the claimed  $\beta$ -chitin complex is a “manufactured”  $\beta$ -chitin complex, as is evident from the entire specification which describes how the claimed  $\beta$ -chitin complex is made by different processes which are summarized at page 10, lines 2-5;
- the claimed  $\beta$ -chitin complex is an “intercalation compound” as disclosed on page 14, lines 14-15, of the specification;
- the  $\beta$ -chitin has a crystal lattice comprising sheets of chitin molecular chains, as disclosed on page 3, lines 26-27, of the specification;
- the guest compound is “introduced” between the sheets of molecular chains, as disclosed on page 14, lines 14-16, of the specification.

In summary, claims 1-14 are pending in the application. Of these, claims 8-14 have been withdrawn, and claims 1-7 have been rejected.

### Telephone Interview

Examiner Lau and Supervisory Patent Examiner Jiang are thanked for the courtesy of the telephone interview held on May 22, 2008. Applicants’ attorney indicated during the interview that Applicants intended to:

- amend claim 1 to recite that the claimed  $\beta$ -chitin complex is an intercalation compound formed by using as a host a  $\beta$ -chitin having a crystal lattice comprising sheets of chitin molecular chains and interposing a guest compound between the sheets of chitin molecular chains;
- point out that the “complex” disclosed in McCandliss et al. does not meet the terms of the claims in this application, in particular because the focus and examples in McCandliss et al. involve  $\alpha$ -chitin, which lacks the structure of stacked sheets of molecular chains which characterizes  $\beta$ -chitin;

- point out that the chitin hydrogel disclosed in common by Drohan et al. and Kim et al. is formed by crosslinking of chitosan, and does not have the structure recited in claim 1 for the claimed  $\beta$ -chitin complex.

The Examiners indicated during the telephone interview that claim 1, as proposed to be amended, in their opinion did not sufficiently distinguish over the prior art, such as the disclosure in the cited Falini et al. article of a naturally occurring mineralized nacre mollusk shell composed of thin layers of  $\beta$ -chitin sandwiched between two thicker layers of silklike proteins (page 2, left column, third paragraph.) In response to the Examiners' comment, claim 1 is amended herein to claim a "manufactured"  $\beta$ -chitin complex, and Applicants will further distinguish Falini et al. by pointing out that the structures disclosed in Falini et al. are not structures formed by guest-host chemistry, which has a specific meaning in the chemical arts.

#### Rejection under 35 USC §101

Claims 1-5 were rejected under USC §101 as being directed to non-statutory subject matter for encompassing a naturally occurring article. Applicants submit that claims 1-5, as amended herein to claim a "manufactured  $\beta$ -chitin complex", clearly do not encompass naturally occurring articles. Therefore, Applicants respectfully request that the rejection be reconsidered and withdrawn.

#### Rejection under 35 USC §102

Claims 1-5 and 7 were rejected under 35 USC §102(b) as being anticipated by McCandliss et al. as evidenced by Falini et al. McCandliss et al. is cited for disclosing a naturally occurring chitin-protein complex which may be obtained from "invertebrate marine organisms having visible shells" (col. 5, lines 40-41). McCandliss et al. cites as examples of such organisms "crustaceans, mollusks, marine benthic organisms and krill fish." Since McCandliss et al. does not indicate which form of chitin is contained in these organisms, Falini et al. is relied upon as evidence that one of the categories mentioned in McCandliss et al., namely mollusks, contains  $\beta$ -chitin sandwiched between protein layers.

Applicants note first that the Office Action characterizes the structure described at page 2, left column, lines 8-13, of Falini et al. as being an “inclusion complex.” Applicants respectfully disagree with that characterization. “Inclusion complex” describes a structure in guest-host chemistry which is formed by inserting molecules of a guest chemical species into spaces originally present in the structure of the guest chemical species. This guest-host relationship is at the molecular level. In contrast, the cited structure of Falini et al. has “thin layers of  $\beta$ -chitin sandwiched between two thicker layers of silklike proteins” (page 2, left column, third paragraph.) It is evident that these thicker layers of silklike proteins are a macromolecular assembly, so that the assembly of  $\beta$ -chitin layers sandwiched between the thicker layers of silklike proteins is not an inclusion complex formed by guest-host chemistry at the molecular level.

Applicants further note that the assembly of Falini et al. does not have the structure of an “intercalation compound” as recited in claim 1, wherein the guest compound is introduced into the original spacing between the sheets of chitin molecular chains in the host  $\beta$ -chitin. As described at the bottom of page 6 of Applicants’ specification, these sheets are held together by Van der Waals forces and hydrogen bonding. It is not possible to insert (i.e., force) such thicker layers of silklike proteins, as disclosed in Falini et al., into the original spacing between these sheets of chitin molecular chains, which are held together by the Van der Waals forces and hydrogen bonding, so as to form an intercalation compound. In contrast, Applicants claim an intercalation compound, and Applicants’ specification teaches on pages 10-14 that the claimed intercalation compound may be formed by introducing or inserting the guest compound between the stacked sheets of molecular chitin chains of the  $\beta$ -chitin by: (1) an immersion-in-melt method, (2) an immersion-in-solution method, or (3) a guest substitution method. That the disclosed methods indeed result in the insertion of the guest compound into the spaces between the sheets of molecular chitin chains is evidenced by the increase in spacing between those sheets, as shown by the X ray diffraction data reported in the specification.

Finally, Applicants note that claim 1, as amended herein, is clearly directed to a manufactured product, whereas McCandliss et al. discloses only a naturally occurring structure.

It is respectfully requested that the rejection of claims 1-5 and 7 over McCandliss et al. be reconsidered and withdrawn for all the reasons set forth above.

Rejection under 35 USC §103

Claims 1-7 were rejected under 35 USC §103 as being unpatentable over Drohan et al. in view of Kim et al. Drohan et al. is cited for disclosing a supplemented chitin hydrogel, which results from “any addition of a supplementary composition or compound, or any combination thereof” (*emphasis added*) to a chitin hydrogel (col. 12, lines 21-62.) Acknowledging that Drohan et al. does not specifically disclose  $\beta$ -chitin, the Office Action cites Kim et al. for teaching that  $\beta$ -chitin is a good candidate material for uses in medical implant devices, wound dressings, drug delivery, etc. (page 2368, left column, lines 13-17.) The conclusion is set forth in the Office Action that it would have been obvious to one of ordinary skill in the art to combine the invention of Drohan et al. with the teaching in Kim et al. of the specific  $\beta$ -chitin.

Applicants submit that even if one of ordinary skill in the art were to be motivated to combine the teachings of Drohan et al. with those of Kim et al. as suggested in the Office Action, the result would not be the manufactured  $\beta$ -chitin complex claimed herein. No combination of the teachings of these two references would lead to an “intercalation compound” as claimed by Applicants, in which a guest compound has been introduced into the spaces between the stacked sheets of chitin molecular chains which form the crystal lattice of  $\beta$ -chitin.

As noted in the Office Action, Drohan et al. makes no mention of the crystalline form of chitin, whereas the structure recited in Applicants’ claims could be obtained only with  $\beta$ -chitin, because  $\alpha$ -chitin has an antiparallel structure as disclosed in Kim et al. (page 2367, right column, lines 3-4 from the bottom.)

Drohan et al. places no emphasis on the process of “supplementing” the chitin hydrogel and teaches that “any addition” may be used (col. 12, lines 20-21.) In contrast, Applicants’ specification discloses the specific processes that result in the formation of the intercalation structure recited in the claims.

As noted above, Kim et al. is cited for teaching that  $\beta$ -chitin will be “a good candidate material for uses in medical implant devices, wound dressings, drug delivery, and so on.” More

accurately, this is a conclusion set forth in another reference, Kurita et al., which is summarized at page 2368, left column, lines 7-17, of Kim et al. As reported by Kim et al., the reason for Kurita et al. to recommend  $\beta$ -chitin over the  $\alpha$ -chitin form is that " $\beta$ -chitin showed much higher reactivity and availability as a starting material for facile chemical modifications." In this context of chemical reactivity, Kim et al. report that they have prepared a semi-interpenetrating network hydrogel membrane composed of  $\beta$ -chitin and poly(ethylene glycol) diaacrylate macromer for possible application in biomedical areas (page 2368, left column, lines 17-21.) For a bandage or wound dressing, Drohan et al. also teaches that a cross-linked chitin hydrogel is used. The chitin hydrogel disclosed in common by Drohan et al. and Kim et al. is formed by crosslinking of chitosan, and does not have the structure of an intercalation compound as recited in claim 1.

In summary, varying combinations of the teachings of Drohan et al. and Kim et al. would not lead to the fabrication of the claimed  $\beta$ -chitin complex. It is respectfully requested that the rejection of the claims over Drohan et al. in view of Kim et al. be reconsidered and withdrawn.

Applicants believe that the application is in condition for allowance. However, should the Examiner believe that there is any remaining issue and it may be resolved to place the application in condition for allowance, the Examiner is invited to contact Applicants' attorney at the telephone number listed below.

In the event this response is not considered to be filed timely, Applicants hereby petition for an appropriate extension of the time for reply. The fee for such petition for extension of time may be charged to Deposit Account No. 502081.

Respectfully submitted,

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